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Report Highlights:

Switzerland has an onerous and slow process for approving products of agricultural biotechnology for food and feed use. In addition, starting in November 2005, a five-year moratorium on approvals for planting of biotech crops or production of genetically modified animals was put into place. The restrictive regulatory environment, combined with strong anti-biotech public sentiment has dampened interest in the Swiss market for biotech products.

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Section I. Executive Summary

Switzerland has an onerous and slow process for approving products of agricultural biotechnology for food and feed use. In addition, starting in November 2005, a five-year moratorium on approvals for planting of biotech crops or production of genetically modified animals was put into place. The restrictive regulatory environment, combined with strong anti-biotech public sentiment has dampened interest in the Swiss market for biotech products.

Section II. Biotechnology Trade and Production

No biotech crops are produced commercially in Switzerland. No request has ever been submitted for approval of a biotech crop for planting in Switzerland. Currently, there is also a moratorium on the production of biotech crops or animals until 2010.

There are no crops under development that will be on the market imminently. Field-testing has been controversial and therefore limited. Since the Federal regulation on field trials was published in 1999, only one authorization for a field trial was requested and granted. Legal challenges went all the way up to Switzerland's Supreme Court before the field trial was ultimately carried out in 2004. Most recently, requests for the approval of three field trials in conjunction with the National Science Foundation's National Research Program have been submitted. Two of the trials are for transgenic wheat and the third is for a transgenic hybrid of wheat and Aegilops cylindrica (jointed goatgrass). These requests are currently under review.

Biotech imports into Switzerland are limited. Few products are authorized and public resistance to biotech has reduced demand for authorized products. Biotech products imported for feed use must be declared to Swiss authorities and are therefore tracked statistically. Feed products declared as biotech accounted for only 0.11% of imports of feed in 2005, down from 1.4% in 2001. Spot-testing is done by the Federal authorities to check for biotech content and proper labeling of feed. Statistics on imports of biotech food for human consumption are not tracked, but spot-checking of products on the market is carried out by cantonal laboratories with guidance from the Federal Office for Public Health.

Section III. Biotechnology Policy

Biotech Approvals

The Swiss Federal Office for Public Health is the competent authority for authorization of biotech products for food use. The Swiss Federal Office for Agriculture is the competent authority for animal feed, plant propagation material for all uses except forestry, as well as plant protection products containing genetically modified organisms, and fertilisers. Immunological products for veterinary use are handled by the Swiss Federal Veterinary Office. The Federal Office for the Environment is the competent authority for plant propagation material for use in forests. In addition to these Federal authorities, applications for both field trials and commercialization must also be reviewed by the Swiss Expert Committee for Biosafety and the Swiss Ethics Committee on Non-human Gene Technology. Once the application is complete, non-confidential documents are made available for public comment for 30 days.

There is currently a moratorium on the approval of biotech plants and animals for production in Switzerland. The moratorium entered into force in 2005 and will last for five years. The

moratorium was the result of a grass-roots movement put to a vote under the Swiss political system, which allows voters themselves to seek changes to the Constitution by referendum as long as at least 100,000 voters sign a petition requesting it. The Federal Government opposed the amendment, stating that it was unnecessary given the stringent approval process in place. The moratorium does not affect approval of imports for food, feed and processing use.

The approval process for biotech products for food, feed and processing use is time-consuming. This, combined with consumer distrust and compounded by retailer anti-biotech polices, has led to few products being submitted for approval.

The following products have been approved for animal feed:

| Name | Raw materials and basic feeds | Approval date |
|---------------------------------|-------------------------------|------------------|
| GTS-Soybeans (Monsanto) | all | 10 December 1997 |
| Bt 176 Corn (Syngenta) | all | 6 January 1998 |
| Bt 11 Corn (Syngenta) | all | 14 October 1998 |
| MON 810 Corn (Monsanto) | all | 27 July 2000 |
| All products approved in the EU | Corn gluten | |
| All products approved in the EU | Corn gluten feed | |
| All products approved in the EU | Corn cob meal | |
| All products approved in | Soybean meal from | |
| the EU | extraction | |
| All products approved in the EU | Soybean meal from pressure | |

There is an exception in force through December 31, 2007 which allows the importation of the above feed products (not the raw material) made from corn and soybeans which have been approved in the United States or Canada. Such products which are imported before December 31, 2007 may be used until December 31, 2008. After those dates, only imports of these feed products made from corn or soy events approved in the European Union (EU) will be allowed.

In addition to the products listed above, trace amounts (up to 0.5%) of other products authorized in the EU would be allowed as adventitious presence in Swiss feed. A similar threshold for products approved in the EU is under discussion for food products as well, albeit with additional conditions to address issues such as potential allergenicity.

The following products have been approved or are under consideration for food use (note that stacked traits must be approved separately):

| Event | Name of | Status | |
|---------------|-----------------|--------------------------------|--|
| | product/company | | |
| MON 40-3-2 | Soy/Monsanto | Registered on 7/19/1996 | |
| Roundup Ready | | Authorized on 12/20/1996 | |
| | | Renewed on 10/31/2002 | |
| Bt176 | Corn/Syngenta | Registered on 11/1/1996 | |
| | | Authorized on 1/6/1998 | |
| | | Requested renewal on 6/27/2002 | |

| | | Under review | | |
|------------------|---|-------------------------------|--|--|
| Bt11 | Corn/Syngenta | Registered on 7/29/1997 | | |
| | | Authorized on 10/14/1998 | | |
| | | Requested renewal on 9/7/2003 | | |
| | | Under review | | |
| T25 Liberty Link | 25 Liberty Link Corn/Bayer Crop Registered on 9/10/19 | | | |
| _ | Science | Under review | | |
| MON810 | Corn/Monsanto | Registered 3/16/1998 | | |
| MaisGard | | Authorized on 7/27/2000 | | |
| | | Requested renewal on 7/1/2005 | | |
| | | Under review | | |
| GT73 Roundup | Colza/Monsanto | Registered 11/30/1998 | | |
| Ready | | Under review | | |
| T25 X MON 810 | Corn/Pioneer Hi-Bred | Registered on 6/22/2000 | | |
| | | Withdrawn | | |
| 1507 Herculex I | Corn/Pioneer Hi-Bred | Registered on 4/9/2001 | | |
| | | Under review | | |
| GA21 Roundup | Corn/Monsanto | Registered on 4/26/2001 | | |
| Ready | | Under review | | |
| NK603 Roundup | Corn/Monsanto | Registered on 8/8/2001 | | |
| Ready | | Under review | | |
| NK603 X | Corn/Monsanto | Registered on 5/8/2002 | | |
| MON810 | | Under review | | |
| 59122 | Corn/Pioneer Hi-Bred | Registered on 4/19/2005 | | |
| | | Under review | | |
| MIR604 | Corn/Syngenta | Registered on 7/1/2005 | | |
| | | Under review | | |
| GA21 | Corn/Syngenta | Registered on 10/28/2005 | | |
| | | Under review | | |
| 3272 | Corn/Syngenta | Registered 6/23/2006 | | |
| | | Under review | | |

Authorizations are for 10 years and companies must apply for renewal of the authorization before it expires. As long as they do so, the product may continue to be commercialized while the application for renewal is under review.

Field Trials

In contrast to the approval process for commercialization, there are specific timeframes set out for the approval process for field trials. Once a complete application has been received by the Federal Office for the Environment, the non-confidential documents are made available for public comment for 30 days. Then the application is forwarded to the Swiss Federal Office for Public Health, the Federal Veterinary Office, the Swiss Federal Office for Agriculture, the Swiss Expert Committee for Biosafety and the Swiss Ethics Committee on Non-human Gene Technology and the competent authority in the canton where the proposed field test will take place. These entities must state their position within 50 days, although the clock stops if any entity requests further information from the applicant. Public meetings in the locality where the test will take place may also be organized.

The Federal Office for the Environment should then issue a permit within 90 days of opening public comment, as long as it is determined that there is no danger to the environment or people and each of the entities outlined above has given its consent. The approval may be linked to conditions related to monitoring and security of the site. Applicants must also

provide a liability guarantee of up to 20 million Swiss Francs (approx. \$16.6 million). The Federal government, its public corporations and institutions and the Cantons are exempt from the liability guarantee requirement.

The following requests have been submitted for field trials:

| Applicant | Application date | Publication for comment | Organism | Trait | Proposed dates of trial |
|----------------------|------------------|----------------------------|---|----------------------|-------------------------|
| University of Zurich | 4/17/2007 | 5/15/2007 | Hybrid of Aegilops cylindrica and Triticum aestivum | Fungus resistance | 2008-2010 |
| University of Zurich | 2/21/2007 | 5/15/2007 | Wheat | Oidium resistance | 2008-2010 |
| EPFZ* | 2/22/2007 | 5/15/2007 | wheat | Fungus resistance | 2008-2010 |

^{*}Swiss Federal Institute of Technology Zurich

According to the Federal Office for the Environment, 29 comments from citizens and 10 opinions of associations were submitted in opposition to the field trials. The majority of the comments (27 out of 29) were submitted about the field trial proposed by the EPFZ to take place in Pully, near Lausanne. All opponents signaled their intention to appeal any approval of a permit.

In spite of public resistance and administrative hurdles to testing and commercialization of agricultural biotechnology products, the overall Swiss biotech industry (including medical and industrial applications) is relatively dynamic. In 2005 there were 229 biotech companies in Switzerland of which 91 biotech suppliers and 138 core biotech companies. On a per capita basis, Switzerland has the world's highest density of biotech companies.

Coexistence

Although no crops are currently produced and a moratorium is in place, Switzerland has proposed draft coexistence rules for comment. Work on this draft legislation has been put on hold as a result of the moratorium and while awaiting the results of the Swiss National Science Foundation's National Research Program on the "Benefits and Risk of the Deliberate Release of Genetically Modified Plants." This research program includes projects to evaluate the impacts of biotech crops on wild relatives, soil fertility and non-target insects as well as coexistence and ethical issues.

Labeling

The Swiss biotech labeling regime is closely aligned with that of the European Union. Labeling is for consumer information purposes. All food and feed products (including petfood) containing/consisting of biotech products and/or produced from biotech products, including products that no longer contain detectable traces, must be labeled. If a product contains 0.9 percent or lower biotech (or biotech derived) content and the content is "adventitious" (i.e. not intentional), the product does not have to be labeled as containing or being derived from biotech. This tolerance is for approved biotech products only; there is no tolerance for unapproved varieties, although there is an exception (up to 0.5% adventitious presence) for feed products that are approved in the EU, even if they are not approved in Switzerland. Imports of food and feed (including petfood) are spot-checked to ensure that they are properly labeled if they have biotech content.

Meat, milk, eggs or other livestock products made from animals fed biotech feed need not be labeled. Products produced using genetically modified microorganisms as processing aids (such as yeasts in the production of wine or beer, or enzymes in the production of cheese) need not be labeled if the biotech processing aid is not present in the final product.

Biosafety Protocol

Switzerland has signed and ratified the Biosafety Protocol. It was implemented with an Ordinance complementing existing rules that were already in place. The Ordinance integrated new elements regarding notification and documentation requirements for exports of GMOs intended for use in the environment. It also set up the national focal point in the Swiss Federal Office for the Environment and provided for Swiss participation in the Biosafety Clearing-House and a mutual alert system with neighboring countries in the event of unintentional transboundary movement of GMOs. No changes were required regarding imports since they were already covered by existing legislation.

LL601 Rice

On August 18, 2006, US Agriculture Secretary Mike Johanns announced that USDA and FDA had been notified by Bayer CropScience that the company had detected trace amounts of regulated genetically engineered (GE) rice in samples taken from commercial long grain rice. The line in question, LL601 "Liberty Link" rice was not considered to present a danger to human health, food safety, or the environment, but it presented a regulatory and trade issue since it was unapproved in the United States and Switzerland. The United States traditionally exports approximately 18,000 metric tons of rice to Switzerland annually, valued at approximately \$7 million.

The Swiss Federal Office for Public Health issued a recommendation for importers to obtain certificates on imports of US long grain rice showing them to be free of LL601 contamination. Certificates issued at origin would be acceptable. If imports are accompanied by a certificate based on the EU sampling and testing methodology, re-testing at destination would not be required, although there would be spot-checking. Spot checks by cantonal control bodies use the EU sampling and testing methodology. The two main retailers, Migros and Coop conducted their own testing of their rice supplies and temporarily removed all US long-grain rice from their shelves. While some US rice brands were eventually returned to the shelves, some shifting to non-US suppliers has taken place.

Section IV. Marketing Issues

The main retailers in Switzerland have taken a strong anti-biotech stance, stocking only non-biotech products and requiring meat to have been produced without biotech feed. Coop, with 35 % of the market is the second-largest retailer in Switzerland and has a clear anti-biotech policy outlined on its website and promotional material. Migros, the largest retailer with 37% of the market, has a similar anti-biotech policy, but does not advertise it as aggresively. The retail market is highly concentrated and controlled by these two retail giants. In addition, they are large players in the importation and distribution of food in Switzerland.

In a recent press release, Coop released the results of an in-house survey, which showed that 85% of Swiss people do not want biotech food. This opposition was noted to be slightly more pronounced among women (88%) than men (81%). The strongest opposition was in the 35-54 age group. 83% of the respondents opposed the use of biotech feed as well. 54% of respondents requested that Coop not stock biotech products, a 10% increase

compared to the results of a similar survey in 2004. In spite of the fact that biotech products are generally not available on the market in Switzerland, 75% of respondents believed that these products were on the market.

Animal products produced from animals fed biotech feed are not required to be labeled in Switzerland. However, due to retailer policies and the fact that the Swiss import tariff regime results in the same price level for biotech and non-biotech feed, Swiss livestock producers have no incentive to use biotech feed.

A recent scandal involving fraudulent corn gluten feed from China, contaminated with urea, melamine and cyanuric acid, highlighted the potential downside of using alternative suppliers in an effort to avoid biotech content. Until recent years, the US was the main supplier of corn gluten feed to Switzerland.